PMD70
A REVIEW OF THE GEOGRAPHIC VARIATIONS IN THE IMPLANT RATE OF TRANSCATHETER AORTIC VALVES IN 14 EUROPEAN COUNTRIES
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OBJECTIVES: Multiple medical reimbursement systems exist in Europe, which may create unequal dissemination and coverage of innovative medical devices. Even in the setting of regularly revised systems, uptake of new technology may be delayed leading to unequal reimbursement. **METHODS:** This study analyzed the 2010 geographical trends of transcatheter aortic valve implantation (TAVI) rates in 14 countries (Medtronic CoreValve System and Edwards Sapien). Implant data were gathered from BIBA Medical Ltd, a UK-based provider of consulting and market analysis services for the medical device industry. In addition demographic and economic data were gathered from Eurostat, a statistical office of the European Union. Regression techniques were used to explore the relationship between implant rate and a number of key variables. **RESULTS:** In 2010, a total of 14,400 TAVI procedures were documented providing an average country-based implant rate of 36.2 per million/Inhabitants. A seven-fold difference in implantation rate existed between the highest and lowest implanting countries (Germany, 77 per million/inhabitants vs. Norway 12 per million/inhabitants). Implant rates were correlated with per-capita GDP (r^2=0,015), health expenditure (r^2=0.15) and number of implanting centers in the country (r^2=0.18). At this time, only two European countries have a dedicated tariff for TAVI that is applicable nationwide and covers both the device and the procedure (Germany – €34,900, France - €28,477). Differences between country-specific tariffs depend on the method of DRG calculation. In Austria, the TAVI tariff was made to equal that of surgical aortic valve replacement. Countries such the UK and Italy have adopted case-by-case funding. In countries such as Belgium and the The Netherlands TAVI is funded by the hospital-based budget. **CONCLUSIONS:** Significant differences in TAVI rates exist among European countries. These observations may help us to better understand unequal patterns of dissemination and coverage of innovative medical devices such as TAVI.

PMD71
RESOURCE USE CAUSED BY IN-OFFICE FOLLOW-UP VISITS FOR CARDIAC IMPLANTABLE ELECTRICAL DEVICES (CIED) IN GERMANY AND THE UNITED KINGDOM
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OBJECTIVES: Expert consensus recommends follow-up (FU) for patients with pacemakers to be performed twice annually, with implantable cardioverter defibrillators or cardiac resynchronization therapy devices four times annually. Most of the routinely scheduled calendar based FU in-office visits do not require further action but contribute to the consumption of limited health care resources. This model estimates the resource use associated with in-office FU visits in Germany and the UK (UK). **METHODS:** Own estimates on the number of FU visits were combined with previously published data on frequency and distance of private and public transport. Recently published data on healthcare personnel resource use were considered to model hospital resource use. Data were modeled until 2015. **RESULTS:** If service providers continue the current service model of routine calendar based in-office visits for CIED patients, about 2.23 mio visits will be needed in Germany, and 836'000 in the UK in 2015. These visits would consume approximately 1.11 mio hours of time in consulting rooms in Germany, and 418,000 hours in the UK. More than 87,000 ambulance transports in Germany and 33,000 in the UK will be required for patients attending FU visits. Patients able to use their own transport will drive about 287 mio kilometers in Germany and 28 mio kilometers in the UK. Workload for physicians, nurses and technicians will reach 1.1 mio hours in Germany, and 406,000 hours in the UK, most of them being provided by physicians. These estimates do not yet include unscheduled and emergency services for CIED patients. **CONCLUSIONS:** The increasing number of in-office FU visits will continue to place a heavy burden on primarily cardiology service providers but also on patients. Technologies such as BIOTRONIK's Home Monitoring can assist hospitals in handling the increasing service demand, free patients from unnecessary travel burden, and ensure adherence to FU.

PMD72
MAMMA CARCINOMA – DATA ANALYSES AND CLASSIFICATION OF TREATMENT IN AUSTRIA
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OBJECTIVES: Cost of illness analysis of breast cancer in Austria using mainly Austrian billing data from intramural and extramural medical treatment based on data from 2006/07 for treatment and degree of severity evaluation. Regarding this project a detailed treatment course classification has to be realized to evaluate the costs and patient ways in Austrian health system. **METHODS:** Main strategy of the project is the combination of data samples detected by Austrian cancer registry and billing data of intramural and extramural single person datasets in combination with intake data of medication for each patient. By combining the recorded data from national statistics, including TNM-classification of each new breast cancer case, and the ICD10-diagnoses, as well as medical individual services, results in classification of breast carcinoma on single person level are achieved. For separation of drug treatment concerning chronical diseases versus cancer indicated drug administration, the half year time span before the first mamma carcinoma detection and the year afterwards is analyzed separately. Special medication groups are assessed in detail and inclusion/exclusion – criteria for costs and treatment are defined. **RESULTS:** Based on this identification an alternative subsumption of new detected carcinoma in six groups (hormone receptor positive, Her 2 positive, hormone receptor positive and Her 2 positive, triple negative, metastasizing mamma carcinoma, early stage mamma carcinoma without chemo therapy in course of treatment) is defined. **CONCLUSIONS:** This classification leads to better insights for cost evaluation representing the state of the art in Austria. This strategy also leads to better overall reliability because the margin of uncertainty of the parameters can be reduced significantly.

PMD73
COMPARISONS OF ANAPHYLACTOID REACTIONS ASSOCIATED WITH DIFFERENT GADOLINIUM PRODUCTS AND IODINATED CONTAST MEDIA USING THE FDA'S ADVERSE EVENT REPORTING SYSTEM
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OBJECTIVES: To review reports of anaphylactoid reactions from gadolinium products (GPs) and iodinated contrast media (ICMs) and to compare events, outcomes, and signals associated with different GPs. **METHODS:** We reviewed ARs in the FDA Adverse Event Reporting System (AERS) and compared reports for GPs and ICMs. We searched FDA-AERS using all reaction terms for ARs linked with GPs and, separately, ICMs. We compared demographics, outcomes, and types of reactions between GPs and ICMs. We compared signal detection results for each GP using proportional reporting ratios (PRRs) and 95% confidence intervals (CI). **RESULTS:** Through March 2010, there were 494 and 2,533 reports for GPs and ICMs, respectively. The data are not confluent since ICM usage preceded GP usage (first ICM event date: 1943, received by FDA: 1969; first GP event date: 1969, received by FDA 1998). Mean ages (± standard deviation) were 49.1±18.0, and 57±18.5, and % male/female were 38%/59% and 40%/43% for GPs and ICMs, respectively. The ARs for GPs and ICMs were serious in 91.7%/97.5% and fatal in 7.5%/13.9%, respectively. Proportions of reports and PRRs (CI) for linear GPs were: gadopentetate dimeglumine = 45.3%, 5.03 (4.34-5.71), gadobenate dimeglumine = 25.9%, 11.41 (9.67-13.46). For the other linear GPs, gadodiamide was reported in 7.9% and gadoversetamide in 0.1%, but the number of cases of use of the agents alone were too small to determine PRR. Gadoteridol, a cyclic GP, was reported in 18.2% of cases with a PRR of 5.27 (4.30-6.45). Overall, PRRs were indicative of safety signals for both GPs and ICMs, 5.9, (5.4-6.4), 7.4 (CI: 7.1-7.7), respectively. **CONCLUSIONS:** FDA-AERS data indicate that GP-associated ARs generate a safety signal comparable to ICMs. Although over 80% of GP-associated ARs were with linear GPs, there was a significant safety signal for one macrocyclic structure GP as well as two linear structure GPs.

PMD74
HOME DIALYSIS MODALITIES: THE DEVELOPMENT OF A FRAMEWORK TO IDENTIFY AND QUANTIFY FAVOURABLE RENAL POLICY AND REIMBURSEMENT FACTORS
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OBJECTIVES: The use of home dialysis modalities such as peritoneal dialysis and home haemodialysis varies across Europe and North America from today <5% in Germany to 28% in Denmark. These differences have often been attributed to reimbursement and renal care organization factors. This analysis was undertaken to quantify the strength of association of potential factors influencing usage of home dialysis modalities with the intent to later facilitate evidence based policy choices. **METHODS:** A 4-pillar framework including 8 different factors (home target, reimbursement level, payment flow, pre-dialysis education, assisted dialysis, home guideline/policy, incentives for home, monitoring/planning tool) was postulated to explain the variation in home dialysis usage across countries. A semi-quantitative scoring algorithm was developed and used to rate the renal care organization of 12 European countries, Canada, and the USA based on publicly available information. A regression analysis was used to explore the relationship between the score and the use of home dialysis modalities as retrieved from the latest available renal registry reports. The most significant factors were identified by analysis of variance. **RESULTS:** A significant (r^2=0.694; p<0.001) correlation was found between the total score and home dialysis usage. Countries like Denmark and Sweden achieving a score of 5 have a 26-28% usage of home modalities. In comparison, Germany had a score of −2 and <5% of dialysis patients are on home modalities. Three factors were especially significant: well funded and independent pre-dialysis education (p<0.001), clinical guideline/policy favouring home modalities (p=0.002), and (absence of) provider-driven demand (p=0.035). **CONCLUSIONS:** The 4-pillar framework appears to be useful to identify gaps in a country renal care policy and decide on further actions to be taken when intending to increase usage of home dialysis modalities. Actions to implement/correct pre-dialysis education, clinical guideline/policy favouring home modalities and (absence of) provider-driven demand should probably be prioritized.

PMD75
PATIENT SELF-TESTING OF ORAL ANTICOAGULATION THERAPY BY COAGUCHEK® XS SYSTEM. RAPID HEALTH TECHNOLOGY ASSESSMENT IN SLOVAK HEALTH CARE ENVIRONMENT
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